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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/489,220 01/21/00 REIDHAAR-OLSON

J 16528A-03890

EXAMINER

020350 HM22/1004
TOWNSEND AND TOWNSEND AND CREW
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ART UNIT F

PAPER NUMBER

DATE MAILED 10/04/00

10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/489,220

Applicant(s)

REIDHAAR-OLSON, JOHN F.

Examiner

Frank W Lu

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 05 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 20-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, claims 1-19 in Paper No.5 is acknowledged. The traversal is on the ground(s) that: (1) there is no search burden for the examination of Groups I and III since "the claims of Groups I and III are both drawn to methods of expression profiling" and (2) there is no undue burden for the examination of both Groups I and II since "the major part of the search for both Group I and II will involve searching the same sequencing" (page 2 of applicant's remarks). The above arguments have been fully considered and the restriction requirement for Group I and III has been withdrawn. However, the arguments have not been found pervasive toward the withdrawal of the restriction requirement nor pervasive toward the relaxation of same such that Group II will be examined. The examiner noticed that the search for Group I will not involve searching nucleotide sequence in claims 20 and 21 of Group II since there is no sequence in any claim of Group I. In the above reasons and in the absence of convincing evidence to the contrary, the restriction election requirement for Group II has been maintained and is hereby made final. Claims 1-19 and 28 will be examined.

Drawings

2. The drawings are objected to for reasons as stated on FORM PTO-948 (Rev. 8-98). Applicant is required to submit a proposed drawing correction in reply to this Office action.

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However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

Claim Objections

3. Claim 1 is objected to because of the following informalities: "is" in line 3 of the claim should be "are". Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-19 and 28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Claims 1-19 and 28 are drawn to a method of expression profiling. The specification (whole specification, specially pages 71-112) discloses that a method of expression profiling comprising the determining the expression levels of two or more nucleic acid in a test sample selected from the group from claims 1, 5-10, or/and 28 and comparing the expression levels in the test sample with expression levels of the same nucleic acids in control samples. However, the specification fails to state specific and substantial asserted utility for two or more nucleic acid in a test sample

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selected from the group from claims 1, 5-10, or/and 28. For example, the specification fails to state a specific and substantial asserted utility of EST (W74293) although the examiner noticed that EST (W74293) was described as highly similar to HYPOTHETICAL 66.9 KD PROTEIN R07B1.8 IN CHROMOSOME X (*Caenorhabditis elegans*) (page 103). A utility directed to laboratory research does not possess a real world use or substantial utility. See for example, *Brenner v Manson* in which materials to be used for research or methods of using those materials for research have raised issues as to whether the utility that is required or constituted in order to carry out further research to identify or reasonably confirm a “real world” context of use. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a “substantial utility.”

Claims 1-19 and 28 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention so it would operate as intended without undue experimentation.

Conclusion

6. No claim is allowed.
7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
September 29, 2000



BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP 1800-165-0
10/2/00